# Novo Nordisk Statement – NovoRapid®

Dear Healthcare Professional

Novo Nordisk has received questions related to a series of adverse event reports received week commencing 7 August 2017 regarding specific NovoRapid® Penfill® batches to which you may or may also not receive queries.

By way of background, a concerned mother of a T1DM patient in Australia contacted Novo Nordisk early in the week to report her daughter had been experiencing significant glucose variability. Based on her own experience as a care giver and responses received in social media after posting her experience, she claims that there must be an issue with some NovoRapid® Penfill® batches in Australia and New Zealand.

We understand that subsequent to the alert to Novo Nordisk on Monday, there was a post within a private social media customer-based forum entitled 'Diabetes Goodies' enquiring whether others had experienced poor blood glucose control with NovoRapid®, resulting in numerous responses and concern from patients. Further, we were also contacted by a journalist from the Gold Coast Bulletin (AUS) seeking clarification on the complaint reported, after being contacted by the concerned mother. The journalist subsequently ran an article which was picked up by additional media outlets and some patients in both Australia and New Zealand.

Insulins such as NovoRapid® are vital, life-saving medications. The issue raised is being treated very seriously, but there is no indication of a causal link between the adverse event reports and a product defect. Furthermore, retention samples from the manufacturing batch raised in the initial query have been retested. Parameters of identity, potency and degradation products were examined and a pH analysis was also performed. The retesting has shown that the batch in question complies with all specifications and as such, quality of the product at time of manufacture has been confirmed. Consequently, our investigation shows that there is no manufacturing issue with NovoRapid®.

All batches of NovoRapid® (indeed all Novo Nordisk products) are thoroughly tested prior to release from their respective production sites, and storage and transportation of all product is verified at all stages until the product is delivered to pharmaceutical wholesalers – so as to ensure storage is within approved conditions (ie temperature, etc). No increased rates of reporting of adverse events of the local (Australian, New Zealand) batches have been noted in other countries where the batches have been supplied.

Novo Nordisk is following all local and global regulatory processes, including logging reported adverse events, reviewing adverse event reporting for NovoRapid®, and raising the reported concern with the TGA and Medsafe as well as with our Global Safety team at Novo Nordisk for further investigation.

It is also important to note that Diabetes is a complex disease – and fluctuations in blood glucose can occur for many reasons beyond the insulin dose given.

NovoRapid® is an important product in the lives of many people with diabetes – so any concern for them is also of concern to us, and that is why we continue to investigate any individual patient query. We will continue to encourage anyone with concerns on this matter

to discuss it with you, their Healthcare Professional, and to also contact our NovoCare® Customer Care Centre on 1800 668 626 (Australia), 0800 733 737 (New Zealand) or AUNRCCC@novonordisk.com.

It is important to re-state investigations show there are no findings indicating an issue with NovoRapid®.

If you continue to have any concerns, please contact Novo Nordisk directly.

Kind Regards
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**Mark Gibson**
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